IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA,

MEMORANDUM DECISION AND ORDER DENYING PLAINTIFF'S

Plaintiff,

MOTION FOR SUMMARY JUDGMENT

v.

Case No. 1:20-cv-173-TS-JCB

RIDLEY'S FAMILY MARKETS, INC.,

Judge Ted Stewart

Defendants.

This matter comes before the Court on a Motion for Summary Judgment¹ filed by Plaintiff the United States of America. For the reasons discussed below, the Court will deny summary judgment as to Plaintiff's Controlled Substances Act (the "CSA") ² claims.

I. BACKGROUND

This case involves claims alleging violations of the CSA.³ Defendant Ridley's Family Markets, Inc. ("Ridley's") is a grocery store chain that operates pharmacies throughout the Intermountain West, including one in Morgan, Utah, which is registered with the Drug Enforcement Administration ("DEA") to dispense controlled substances.⁴ On February 19, 2019, a DEA diversion investigator opened an investigation into the Morgan Ridley's pharmacy after a

¹ Docket No. 98 (SEALED).

² 21 U.S.C. § 801 et seq.

³ Docket No. 26.

⁴ Docket No. 98 ¶¶ 2–3 (SEALED).

doctor reported that his former employee, S.M., had forged prescriptions for herself and her husband, M.M., using the doctor's signature.⁵

The investigation revealed that over several years, Ridley's dispensed at least 167 prescriptions for controlled substances to S.M. and M.M. Plaintiff claims that many of the prescriptions exhibited "red flags" that the pharmaceutical industry associates with illegitimate prescriptions, including suspicious or stamped signatures, dangerous drug combinations, irregular dispensing intervals, odd dosages and pill quantities, cash payments, early fills, errors or missing information, brand name requests, patient calling in her own prescription, pattern prescribing, and other odd behavior.⁷

Plaintiff filed suit against Ridley's on December 4, 2020, alleging that Ridley's dispensed controlled substances in violation of 21 U.S.C. § 842(a)(1) and § 829, and their implementing regulations 21 C.F.R. § 1306.04 and § 1306.06.8

On February 20, 2024, Plaintiff filed a Motion for Summary Judgment. 9 Defendant filed its Opposition on April 26, 2024. 10 Plaintiff filed its Reply on May 24, 2024. 11

II. LEGAL STANDARD

Summary judgment is proper if the moving party can demonstrate that there is no genuine issue of material fact and it is entitled to judgment as a matter of law. 12 In determining whether a

⁵ *Id*. ¶ 7.

⁶ Docket No. 143, at 18.

⁷ Docket No. 98, ¶¶ 33–71 (SEALED).

⁸ Docket No. 2.

⁹ Docket No. 98 (SEALED).

¹⁰ Docket No. 137 (SEALED).

¹¹ Docket No. 143.

¹² FED. R. CIV. P. 56(a).

genuine dispute of material fact exists, the Court considers whether a reasonable jury could return a verdict for the nonmoving party in the face of all the evidence presented. ¹³ "An issue of fact is 'material' if under the substantive law it is essential to the proper disposition of the claim." ¹⁴ The Court is required to construe all facts and reasonable inferences in the light most favorable to the nonmoving party. ¹⁵

"The movant bears the initial burden of making a prima facie demonstration of the absence of a genuine issue of material fact." Once a movant has carried its initial burden, "the burden shifts to the nonmovant to go beyond the pleadings and 'set forth specific facts' that would be admissible in evidence in the event of trial from which a rational trier of fact could find for the nonmovant." 17

III. DISCUSSION

Plaintiff seeks summary judgment that Defendant violated the CSA by knowingly dispensing illegitimate prescriptions. In support, Plaintiff presents purported undisputed facts and circumstantial evidence that Ridley's pharmacists filled S.M.'s prescriptions despite recognizing red flags indicating their illegitimacy. Plaintiff also seeks summary judgment on Defendant's affirmative defenses, which will be addressed in a separate order. Defendant responds that summary judgment is precluded because the undisputed facts do not show that the pharmacists

¹³ See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Clifton v. Craig, 924 F.2d 182, 183 (10th Cir. 1991).

¹⁴ Adler v. Wal-Mart Stores, Inc., 144 F.3d 664, 670 (10th Cir. 1998).

¹⁵ See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Wright v. Southwestern Bell Tel. Co., 925 F.2d 1288, 1292 (10th Cir. 1991).

¹⁶ Adler, 144 F.3d at 670.

¹⁷ *Id.* at 671 (quoting FED. R. CIV. P. 56(e)).

acted with the requisite state of mind under the CSA, and there are disputed material facts regarding red flags and the pharmacists' understanding of them.

Under the CSA, controlled substances can only be issued by a valid prescription. 18 Pharmacists share a "corresponding responsibility" with an issuing provider to ensure that a prescription is issued "for a legitimate medical purpose." A pharmacist who "knowingly" dispenses a prescription that was not issued "in the usual course of professional treatment" violates the CSA.²⁰ "Knowingly" includes "willful blindness."²¹

To prove "willful blindness," the plaintiff must show that the defendant (1) "subjectively believe[d] that there [was] a high probability that a fact exist[ed]" and (2) took "deliberate actions to avoid learning of that fact."22 "[T]he Government is entitled to rely on circumstantial evidence and the benefit of the favorable inferences to be drawn therefrom" to establish deliberate ignorance.²³ However, proving subjective belief and deliberate ignorance is a high burden, as "it is a rare occasion when [the plaintiff] can present evidence that the defendant deliberately avoided knowledge."24

As this Court has previously concluded, circumstantial evidence of willful blindness in a pharmacy context can include "the existence of and failure to investigate red flags." Red flags,

¹⁸ 21 U.S.C. § 829(a)–(c).

¹⁹ 21 C.F.R. § 1306.04(a).

²⁰ *Id*.

²¹ Global-Tech Appliances, Inc., v. SEB S.A., 563 U.S. 754, 767–68 (2011).

²² *Id.* at 769.

²³ United States v. Delreal-Ordones, 213 F.3d 1263, 1268 (10th Cir. 2000) (quoting United States v. Hanzlicek, 187 F.3d 1123, 1133 (10th Cir. 1998)).

²⁴ United States v. de Francisco-Lopez, 939 F.2d 1405, 1409 (10th Cir. 1991).

²⁵ Docket No. 56, at 5 (citations omitted); see also United States v. Otuonve, 995 F.3d 1191, 1212 (10th Cir. 2021) (affirming a pharmacist's conviction under 21 U.S.C. § 841(a)(1)

undefined by federal law, are "indicators of potential diversion" based on "industry standards" discussed by "pharmacy experts . . . in various administrative proceedings." The crux of this case, then, is whether the undisputed material facts show that the circumstantial evidence, namely the red flags present, demonstrate as a matter of law that Ridley's pharmacists knowingly filled illegitimate prescriptions or were willfully blind in doing so.

It is undisputed that Ridley's pharmacists Deanna Reyna, ²⁷ Casey Allen, and David James received training on the red flag standard. ²⁸ Additionally, both DEA agents and Ridley's pharmacists testified that certain warning signs are generally-recognized red flags indicative of diversion, including: incorrect or suspicious signatures;²⁹ incomplete or mistaken information;³⁰

because, among other things, he failed to investigate red flags in connection with prescriptions in violation of 21 C.F.R. § 1306.04(a)); Heartland Pharmacy, Inc. v. Rosen, No. 21-14037-CV-MIDDLEBROOKS, 2021 WL 650350, at *4 (S.D. Fla. Feb. 18, 2021) ("[P]harmacists violate . . . 21 C.F.R. § 1306.04(a)[] when they fail to identify and resolve the red flags that are part of the prospective drug use review . . . and subsequently knowingly fill prescriptions without resolving these red flags during this review.") (internal quotation marks and citation omitted); United States v. City Pharmacy, LLC, No. 3:16-CV-24 (BAILEY), 2017 WL 1405164, at *4 (N.D.W.V. Apr. 9, 2017) (granting summary judgment against a pharmacist for violating 21 U.S.C. § 842(a)(1) when concluding that the "red flags [were] so obvious that only those who [were] deliberately ignorant would fill the prescription") (citation omitted).

²⁶ Docket No. 98, Ex. P at 27: 12–16 (SEALED); see also id., Ex. F at 102:19–20 (SEALED) ("[A] prescription can be legitimate but still have red flags").

²⁷ The Court refers to Ms. Reyna by her current, preferred last name rather the last name she used when she worked at Ridley's.

²⁸ *See* Docket No. 98 ¶ 28.

²⁹ Id. Ex. P at 27:2 (SEALED) ("signatures on prescriptions not being correct"); Ex. E at 144: 4-5 (SEALED) ("signature was wrong from what I have previously seen"); Ex. F at 112:21– 22, 113:4 (SEALED) (different pens and different ink colors); Ex. G at 110:19–25 (SEALED); Ex. H at 63:1 (SEALED) ("identical or stamped signatures").

³⁰ Id. Ex. P at 27:3 ("prescription not meeting what's set forth in 1306.05"); Ex. E at 144:5-6 (SEALED) ("if it didn't have any of the other information on the prescription"); Ex. F at 112:19-20 (SEALED) ("[s]ee if the date has been adjusted").

cash payments, especially if patients paid with insurance previously;³¹ dangerous drug combinations;³² unusual or high tablet counts;³³ early fills or increased number of fills;³⁴ and high doses or irregular dosing changes³⁵ among other signs.

There is no dispute that Ridley's pharmacists dispensed prescriptions to S.M. and M.M. between 2017–2019 and many of those prescriptions exhibited red flag(s). These included dispensing dangerous combinations of drugs a few days apart from each other or on the same day;³⁶ dispensing high volumes of single ingredient opioids ranging from 90–180 tablets;³⁷ filling prescriptions with inconsistent or rapidly increasing supply intervals, dosages, and quantities; 38 accepting cash payments; 39 filling prescriptions early; 40 and dispensing similar prescriptions to S.M. and M.M. in a form of pattern prescribing. 41

³¹ Id. Ex. F at 103:5–6 (SEALED) ("prescription is not being billed to a third party"); Ex. P at 27:4 ("cash payments").

³² Id. Ex. P at 27:4–6 ("[t]rinity combinations for controlled substances, which typically would include a [sic] opioid, a benzodiazepine, and carisoprodol"); Ex. F at 102:10–12 (SEALED) ("possible drug interactions"); Ex. G at 108:12–13 (SEALED) ("does this go with this drug"); Ex. H at 105:15-16 (SEALED) ("I also take into account other co-prescribing of things such as muscle relaxers, benzodiazepines or stimulants").

³³ Id. Ex. H at 63:1–2 (SEALED) ("large quantities of opioids, large quantities of carisoprodol").

³⁴ Id. Ex. F at 104:7 (SEALED) ("frequency" of "[w]hen he last picked up or she last picked up"); Ex. G at 108:11-12 (SEALED) ("is this early").

³⁵ *Id.* Ex. E at 144:3–4 (SEALED) ("if [the dose] was way too high"); Ex. G, at 108:12 (SEALED) ("is this dose [] different than usual"); Ex. F at 112:20–21 (SEALED) ("strength of the medication").

³⁶ Docket No. 98 ¶¶ 33–37.

³⁷ See id. ¶¶ 38–39.

³⁸ See id. ¶¶ 41, 43–45.

³⁹ See id. ¶¶ 46–47.

⁴⁰ See id. ¶¶ 50–53.

⁴¹ See id. ¶¶ 65–66.

However, the undisputed facts are insufficient to demonstrate that the pharmacists knowingly violated the CSA as a matter of law. As mentioned above, the willful blindness standard requires Plaintiff to show that the pharmacists (1) "subjectively believe[d] that there [was] a high probability a fact exist[ed]" and (2) took "deliberate actions to avoid learning of that fact."

First, Plaintiff has not met its burden showing that the pharmacists "subjectively believe[d] that there [was] a high probability" that the prescriptions were illegitimate. ⁴³ To prove that the red flags were obvious, Plaintiff offers a list of every prescription the pharmacists filled for S.M., showing that nearly every prescription exhibited red flags. ⁴⁴ While these red flags, in isolation, may be compelling evidence that the pharmacists should have recognized the "high probability" that the prescriptions were illegitimate, the amount of red flags by itself does not show, as a matter of law, that the pharmacists actually recognized the red flags. Indeed, whether a red flag is present depends on a pharmacist's professional judgment and specific circumstances of the prescription, including a holistic review of the prescription, patient, and situation. ⁴⁵ Furthermore, two of the pharmacists testified that they did not know the prescriptions were

⁴² Global-Tech Appliances, Inc., 563 U.S. at 769.

⁴³ *Id*.

⁴⁴ Docket No. 98, Ex. A.

⁴⁵ Docket No. 137-4, at 107:4–18 (SEALED) ("There has never been a time where I look at one prescription and look at one drug and don't take into account whether it's the drug strength or other factors, such as the practitioner's specialty, into account. There's always additional things that I'm looking at . . . I look at several things, but it's . . . never or rarely one very small thing such as quantity. . . because there's so many other factors that come into play."); Docket No. 135-17, at 61:3–6 ("I think the important part is the second sentence where it says it's the totality of the circumstances. The facts and circumstances that are provided regarding each unique situation, case, prescription, so forth.").

illegitimate when they dispensed them. 46 Although self-serving, this evidence creates an issue of material fact as to whether the pharmacists "had *subjective* knowledge of [their] [violating] behavior."47

In another attempt to prove that the red flags were clear, Plaintiff presents guiding documents regarding red flags from the Food and Drug Administration, the Center for Disease Control, the pharmaceutical industry, and the DEA. This evidence indicates that red flags are a common standard in the pharmaceutical industry, but there is no codified standard for what constitutes a red flag and how they should be resolved under the CSA. This ambiguity about what constitutes a red flag and a pharmacist's standard of care indicates there is a genuine issue of material fact about whether the pharmacists should have recognized the red flags in this case.

Second, Plaintiff also did not show, as a matter of law, that the pharmacists took "deliberate actions to avoid learning" that the prescriptions were illegitimate. ⁴⁸ There is evidence that the pharmacists attempted to resolve some red flags by physically or mentally filling out Ridley's Good Faith Dispensing Checklist, calling the prescriber, or checking the DOPL database and patient profiles. ⁴⁹ Plaintiff questions whether these actions resolved the red flags, and both parties blame each other for the loss of the missing checklists, ⁵⁰ but whether the evidence shows the pharmacists resolved the red flags or turned a blind eye to them remains a factual issue for the jury to resolve.

⁴⁶ Docket No. 137-6, at 23:12–15, 49:2–5 (SEALED); Docket No. 137-12, at 311:21–312:7 (SEALED).

⁴⁷ de Francisco-Lopez, 939 F.2d at 1409.

⁴⁸ Global-Tech Appliances, Inc., 563 U.S. at 769.

⁴⁹ Docket No. 137-12, at 145:20–24, 307:3–15 (SEALED); Docket No. 137-11, at 117:5–9 (SEALED).

⁵⁰ Docket No. 137, at 12–13 (SEALED); Docket No. 143, at 18 n.34.

Ultimately, the question of whether "red flags existed, whether they were adequate to establish that pharmacists subjectively believed there was a high probability that the prescriptions were legitimate, and whether they were adequately resolved is a fact question."53 Both parties must present evidence to a jury about a pharmacist's corresponding responsibility in

⁵¹No. 3:16-CV-24 (BAILEY), 2017 WL 1405164 (N.D. W. Va. Apr. 19, 2017).

⁵² *Id*.

⁵³ Cherokee Nation v. McKesson Corp., No. CIV-18-056-RAW, 2021 WL 1200093, at *6 (E.D. Okla. Mar. 29, 2021) (internal quotation marks and citation omitted) (denying a motion to dismiss under the CSA); see also In re Nat'l Prescription Opiate Litig., No. 1:17-md-2804, 2019 WL 3917575, at *7 n.8 (N.D. Ohio Aug. 19, 2019) (internal quotation marks and citation omitted) ("[D]etermining whether a specific order is suspicious and the timing of when it is discovered involve questions of fact that will necessarily depend on the totality of individual circumstances").

dispensing controlled substances, how red flags fit into that standard of care, and whether the red flags present here showed that the pharmacists recognized the diversion but deliberately ignored it.⁵⁴ Viewing the evidence in the light most favorable to Defendant, Plaintiff has not met its burden to establish that it is entitled to judgment as a matter of law. Thus, the Court will deny Plaintiff's request for summary judgment on the issue of whether Defendant violated the CSA.

IV. CONCLUSION

It is therefore

ORDERED that Plaintiff United States' Motion for Summary Judgment (Docket No. 98) is DENIED; It is further

ORDERED that Plaintiff and Defendant file a Status Report within ten (10) days of this Order proposing trial dates and anticipated trial duration, after which the Court will set the matter for trial and set the remaining pretrial deadlines.

DATED January 21st, 2025.

BY THE COURT:

TED STEWART
United States District Judge

⁵⁴ *United States v. Lovern*, 590 F.3d 1095, 1100 (10th Cir. 2009) (finding that contradicting experts in a CSA violation were admissible because the jury "remained free to sort out all the competing proof: the question what constitutes usual medical practice remained, at all times, within its province").